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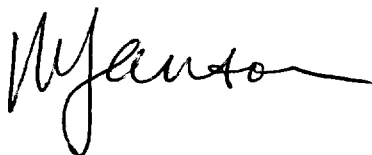
May 27, 1999

To: Dockets Management Branch {HFA-305}
Docket No. 98N-1265
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

I object to the draft MOU being proposed by the FDA. In particular, I object to the definition of "inordinate amount," which restricts the availability and the right to obtain medically necessary compounded medications by limiting the number of prescriptions that can be shipped across state lines from specialized compounding pharmacies.

In my medical practice, some of my patients depend on compounded medications that they cannot get other than from compounding pharmacies. Either they have not responded well to pre-fabricated medications, or those that are available are not meeting their needs. These pharmacies have met a need that the larger pharmaceutical companies have failed to address. They are not "manufacturing drugs" but compounding medications in response to specific physician prescriptions for specific patients. It would be a disservice to those patients to restrict the availability of those medications, and it would interfere with the doctor-patient-pharmacist relationship. I urge you to reconsider and abandon any restriction such as the one being proposed.

Sincerely,



Michael Janson, M.D.

98N-1265

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